UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al. ex rel.* MARY BIXLER WOOD, Plaintiff, v. SIEMENS MEDICAL SOLUTIONS USA, INC., SIEMENS HEALTHCARE DIAGNOSTICS INC., and SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS GMBH, Defendants.	No. 21-cv-1947 (MKB) (JRC) Hon. Margo K. Brodie, U.S.D.J.

SIEMENS' MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE AMENDED COMPLAINT WITH PREJUDICE

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Defendants Siemens Medical Solutions, Inc. and Siemens Healthcare Diagnostics Inc. (collectively, "Siemens")[1] respectfully submit this memorandum of law in support of Siemens' motion to dismiss Plaintiff-Relator Mary Bixler Wood's Amended Complaint with prejudice.

PRELIMINARY STATEMENT

Relator's case is meritless, but that has not deterred her from filing it twice and continuing to pursue it even after ***two*** U.S. Attorney's Offices declined to support it. Relator alleges that Siemens failed to ship its *in vitro* diagnostic assays ("IVDs") within specific temperature ranges, which Relator erroneously asserts are required by the FDA. From there, Relator hypothesizes that *if* a product is not kept within a certain temperature range during shipment, the product *could* degrade, which *could* lead to an erroneous patient result, which *could* lead to a laboratory submitting a claim for reimbursement, which *could* result in a payment by the government, which *could* constitute a fraud on the government and thereby *might* violate the federal False Claims Act ("FCA") and its state analogs. But as the Amended Complaint and its exhibits make plain, Relator has alleged no facts showing that any IVD was ever shipped by Siemens in a manner that was not compliant with FDA regulations, let alone in a manner that caused damage and resulted in anyone seeking government reimbursement for a compromised test result. Having failed to allege even a single false claim, Relator has no viable case to pursue.

Relator is a former consultant who very briefly worked at Siemens in 2016 to assist in Siemens' analysis of potential ways to enhance Siemens' methods for shipping its assays. Instead of doing her job, Relator misused her access to try to concoct a *qui tam* action—at least her second against medical device companies in the past few years.[2] During her very short

[1] Defendant Siemens Healthcare Diagnostics Products GmbH ("GmbH"), a foreign entity domiciled outside the United States, has never been served and Relator has advised she intends to dismiss GmbH with prejudice.

[2] *See U.S. ex rel. Wood v. Avalign Techs., Inc.*, No. 14 Civ. 4958 (ER).

tenure at Siemens, as demonstrated by her own Amended Complaint, Relator misappropriated confidential documents, surreptitiously recorded conversations, and made alarmist allegations about topics for which she had incomplete or simply no understanding. She then filed an action in SDNY, setting forth unfounded and implausible allegations that accused Siemens of violating non-existent regulations and putting millions of patients at risk. After a lengthy Government investigation by the U.S. Attorney's Office in that district (supported by the FDA), with which Siemens fully cooperated, the Government and all 28 named states and the District of Columbia *declined* to intervene. But as soon as Siemens sought leave to file a motion to dismiss, Relator maneuvered to preempt Siemens' motion by voluntarily dismissing the action herself. Then, unbeknownst to Siemens, several months later she refiled a substantially-identical complaint in this District. This time, the U.S. Attorney's Office for the Eastern District of New York investigated, and yet again the Government and all 30 named states and D.C. *declined* to intervene. Nearly six years into this saga, it is time for this case to end and Wood's baseless accusations to be put to rest.

First, Relator's allegations are implausible on their face. The breadth of Relator's claims—a multi-year and ongoing conspiracy implicating Siemens' entire portfolio of assays (billions of which are shipped and sold annually)—would, if true, necessarily lend themselves to evidence of widespread product failures, rampant erroneous test results, misdiagnoses, voluminous customer complaints, and decisive regulatory attention. Yet Relator has not alleged and cannot allege ***any*** of that. Relator cannot identify even a ***single*** test that degraded due to Siemens' shipping practices and produced an erroneous patient result—much less a single instance in which the government paid for such a compromised test result. Nor does she allege a single complaint from Siemens' customers—highly-sophisticated, intensively-regulated private

and government testing labs—regarding an erroneous test result caused by Siemens' industry-standard shipping practices. Nor does she allege a single adverse finding by the FDA or a single instance in which the government declined to pay for Siemens' products because of its shipping practices, even in the six years since she filed her claims. Her failure to allege any such facts reveals the fatal implausibility of her claims.

Second, Relator has not pleaded her claims with the particularity required by Rule 9(b). Relator has not alleged with particularity (or even generality) that: (i) any shipment was exposed to excessive temperatures; (ii) any product was damaged; (iii) Siemens' shipping practices caused any inaccurate test results; or (iv) Siemens submitted or caused to be submitted a false claim for reimbursement to the government, the *sine qua non* of an FCA claim.

Third, Relator has failed to plead falsity, a crucial element of any FCA claim. Relator does not allege the government paid for tests that were not performed or that Siemens made or caused to be made a factually false statement in connection with government reimbursement. Rather, Relator premises her case on a theory of "legal falsity," asserting that Siemens made or caused others to falsely certify Siemens' compliance with its regulatory obligations. This theory has three fatal flaws: (a) Relator has not alleged—and cannot allege—any regulatory violation; (b) even if she could, a violation of FDA regulations does not create FCA liability; and (c) even if it did—which it does not—Relator has not identified a single such certification.

Fourth, Relator has failed to plead materiality, yet another essential element of the FCA. Relator has failed to plead any violation likely to influence the government's decision to pay for Siemens' products, because Relator's pleading and the undisputed record demonstrate that any purported violation is *im*material as a matter of law. Tellingly, Relator does not allege that the government has rejected reimbursement or taken any action regarding past, current or future

payments since Relator filed her first complaint six years ago. The fact that the federal government and every state named in the Amended Complaint ***twice*** **declined to intervene** in this action further shows that Relator's allegations are immaterial—and without merit.

STATEMENT OF FACTS[3]

A. Siemens' IVDs

Siemens is an innovative manufacturer of medical devices, including IVDs (also known as "assays"), which are used to measure chemicals, hormones, or other biological substances in patient samples (*e.g.*, blood draws) for the purposes of informing medical diagnosis and/or treatment. Am. Compl. ¶¶ 2–4, 12. Siemens has developed hundreds of assays for the U.S. market, each of which has been cleared, approved, or otherwise authorized by the FDA for marketing and sale. *See id.* The IVDs typically come in the form of reagents (*i.e.*, materials designed to react with the chemical or biological substance being measured in the patient's blood sample) that are used on multi-assay analyzer platforms manufactured by Siemens. *Id.* ¶¶ 2, 4. Siemens also provides calibrators and controls, which are used to confirm the assays received by the customer will "function properly in a laboratory setting" *prior* to their being used on patient samples for testing purposes. *Id.* ¶ 96; 21 C.F.R. § 862.1660; *see also infra* at 13.[4]

B. FDA Regulations Do Not Require Shipment at Long-Term Storage Temperatures

The core premise of Relator's complaint is that any deviations during short-term *shipping* from the temperature ranges appropriate for long-term *storage* of IVDs necessarily results in the IVD being adulterated or misbranded. This is not so. Relator relies on FDA regulations governing approval and labeling of IVDs, but she fundamentally misreads and misrepresents

[3] The following facts are alleged in the Amended Complaint, included in the attached exhibits, incorporated by reference, or are those for which the Court can take judicial notice.

[4] Relator does not allege that calibrators and controls are subject to reimbursement by the government, nor are there any codes for such reimbursement in the list appended to the Amended Complaint. *See* Am. Compl. Ex. 2.

those regulations. FDA regulations do not require manufacturers to **ship** IVDs under the same conditions that their labeling provides for long-term storage to maintain shelf life or, indeed, under any particular conditions. Instead, the FDA oversees the shipping of IVDs through Current Good Manufacturing Practice ("cGMP") requirements, which mandate only that shipping containers "protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution." 21 C.F.R. § 820.130.

i. FDA regulations for approval and labeling of IVDs do not include shipping temperatures

Neither the FDA regulations related to the approval of medical devices, nor those related to labeling—the regulations upon which Relator relies—address IVD shipping temperatures.

The IVDs at issue here were approved or cleared by the FDA through a Pre-Market Approval ("PMA") application or a Pre-Market Notification, also known as a "510(k)." Use of a PMA or 510(k) depends on the characteristics of the device and whether it has a pre-existing equivalent in the market. *See* Am. Compl. ¶¶ 31–42. An IVD PMA application requires manufacturers to provide a description of the manufacturing, processing, packing, storage, and installation of the device, but *not* the methods or conditions for shipping, including temperature conditions. 21 C.F.R. § 814.20(b)(4)(v). As part of a 510(k) submission, manufacturers are required to submit data on, among other things, the device's design, operational principles, materials used, labels, clinical tests, and intended use. 21 C.F.R. §§ 807.87, 807.92. But as with PMAs, data on shipping conditions (including temperature) is not required. *Id.*

Relator does not allege that any of Siemens' specific PMA or 510(k) submissions were deficient. And Relator's suggestion that short-term shipping temperatures are part of the approval process is misleading and wrong. It appears to be based solely on a misreading of an outdated FDA regulation. *See* Am. Compl. ¶ 43 (citing 38 Fed. Reg. 7096 (Mar. 15, 1973)). Yet,

even in that regulation, the referenced "conditions of temperature" referred only to long term "storage instructions," not to shipping conditions. 38 Fed. Reg. 7096, 7098–101.[5]

Relator also alleges that new FDA submissions are required when modifying an IVD, including with respect to "*storage* temperature changes." Am. Compl. ¶¶ 34, 37, 41 (emphasis added). That may be, but as with the initial approval, data on shipping conditions is not required. While a PMA supplement is required for certain "change[s] affecting the safety or effectiveness of the device," the types of changes listed in the relevant regulations do not include shipping. 21 C.F.R. § 814.39(a). The same is true of 510(k) supplements. *See* FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, at 27 (Oct. 25, 2017).[6]

The FDA does oversee the labeling of IVDs. Am. Compl. ¶¶ 53–57. FDA regulations concerning labeling say nothing, however, about shipping conditions; they do not require a manufacturer to make claims about shipping conditions and they do not mandate that manufacturers ship IVDs within their storage conditions. *See* 21 C.F.R. § 809.10(b). The FDA requires that product labels must include "appropriate *storage* instructions adequate to protect the stability of the product," (*i.e.*, to maintain its labeled shelf life) which includes temperature "when applicable" and an "expiration date based upon the stated *storage* instructions." *See id.* §§ 809.10(a)(5), (a)(6)(i), (b)(5)(iv), (d)(1)(v), (e)(1)(vi) (emphasis added).[7] Consistent with these regulations, Siemens' IVD labels—like others across the IVD industry—make no claim

[5] Although the FDA does not mandate specific shipping temperatures, the FDA has ample opportunity as part of the PMA and 510(k) approval processes to review stability and stress testing results, *see* Am. Compl. ¶¶ 54, 99, which provide the scientific foundation for Siemens' shipping practices. *See* 21 C.F.R. § 814.20(b)(6)(i); FDA, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications* at 22 (July 28, 2014).

[6] *Available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.

[7] The omission of any requirements regarding shipping is not inadvertent or the result of failure to consider the topic. The FDA requires information on shipping conditions in other contexts when it believes them necessary. For example, when referring to *specimen* collection (as opposed to IVDs), the FDA requires labels to include "[r]ecommended storage, handling or *shipping* instructions." 21 C.F.R. § 809.10(b)(7)(iv) (emphasis added).

about required shipping conditions; quite the opposite, they refer only to long-term storage requirements. *See* Exs. A-C. (selection of Siemens IVD labeling).[8]

ii. FDA oversight of IVD shipping through cGMP requirements

Although the FDA does not oversee shipping conditions through its device approval and labeling oversight, shipping of IVDs is not unregulated. The FDA oversees the manufacture and distribution of IVDs through its cGMP requirements, which are codified under its Quality System Regulations ("QSR"). 21 C.F.R. § 820.1. These regulations intentionally provide device manufacturers with flexibility to adopt methods that are efficient and cost-effective to deliver safe and effective devices.[9] Contrary to what Relator asserts, *see* Am. Compl. ¶¶ 44–52, these regulations do **not** mandate any specific shipping methods or temperatures. Rather, the regulations require only that manufacturers identify and use shipping containers that "protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution." 21 C.F.R. § 820.130. To do so, IVD manufacturers are directed to "establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling." *Id.* § 820.140.

On their face, these regulations afford manufacturers broad flexibility to determine the appropriate shipping conditions for their products based on the attributes of the specific products,

[8] Exhibits referenced in this memorandum (other than those attached to the Amended Complaint) are attached to the accompanying Declaration of Joshua A. Goldberg dated June 17, 2022. Relator's allegations cover thousands of products. The exhibits referenced here are intended to be an illustrative sample. Relator's allegations about the labeling for Siemens' IVDs incorporates the labeling by reference, and thus the Court may consider them as part of the complaint. *See DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010). The Court may likewise rely on the labeling and other material filed and publicly available on the FDA website. *Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 134 (E.D.N.Y. 2018) ("District courts may take judicial notice of public records of the FDA on a motion to dismiss[.]"); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 152 (E.D.N.Y. 2018) (taking judicial notice of various FDA public records, such as citizen petitions, and draft guidance documents in deciding a motion to dismiss).

[9] *See* FDA, Quality System (QS) Regulation/ Medical Device Good Manufacturing Practices, *available at* https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices (last updated February 23, 2022).

which vary widely among the various IVD manufacturers. Consistent with the regulatory language, industry publications provide guidance and standards about best practices. For instance, the Clinical and Laboratory Standards Institute publishes guidelines for designing and conducting stability testing to account for shipping conditions. *See* CLSI EP25-A, 2009 Evaluation of Stability in *In Vitro* Diagnostic Reagents [September 2009] at 10. If devices were required to be shipped as stored (as Relator maintains), such guidance would be superfluous.

C. Siemens' IVD Shipping Procedures

Siemens maintains procedures and instructions, supported by testing, decades of deep scientific and technical experience, and industry standards, to ensure its products are appropriately shipped, stored, and used.

i. Siemens' evaluation of temperature effects during IVD design

Siemens evaluates the impact of temperature (and other factors) on IVDs beginning early in the research and development process. Among other things, Siemens performs design and process Failure Modes and Effects Analyses ("FMEAs") as part of its standard procedures within the evolution of a product design. Am. Compl. ¶¶ 101–03 & Exs. 8, 9–10F. Relator focuses on the troponin assay as an example of how the FMEA developed early in the R&D process is supposedly an indication of a product failure in a subsequently FDA-approved device. *Id*. ¶¶ 141–42 & Exs. 9, 27. But as the exhibits themselves show, the purpose of the FMEAs is to brainstorm during product development the *potential* risks and *potential* mitigation efforts in connection with evolving design development *prior* to finalization of a design and ultimate manufacture and distribution, including risks associated with shipping that could result from various design attributes. *Id*. Ex. 8 at 32 ("The FMEA is a bottom-up approach as it starts from a *potential* failure in a component and identifies the system-level hazard caused by it.") (emphasis added), 33 ("The column inputs that should be included in an effective FMEA include: . . .

[c]ontrols that are in the design concept or are to be added to reduce either severity or frequency of harm[,] [i]mplementation and evaluation of effectiveness of the controls[,] [r]escoring of risk[, and] [a]cceptability of residual risk after controls are applied."). The FMEAs do not (and in fact could not) represent evidence of actual failures of the final products, and they do not constitute an admission that a finished product is actually susceptible to any risk identified early in the product's development. In fact, they show the opposite—that a potential risk was considered, evaluated, and mitigated during the R&D process prior to finalizing a suitable product design. *See id.* Exs. 8–10F. After the applicable risk control measures have been taken into consideration, the probability of risk for a given product/risk scenario is reduced to "Extremely Unlikely" for each FMEA entry and the final risk index for the IVD is either "Negligible Health Risk" ("NR") or "Low Health Risk" ("LR"). *See id.* Exs. 9–10F, 27, 46.[10]

ii. Siemens' determination of shipping methods through rigorous testing

As detailed in Relator's exhibits, Siemens has used comprehensive and rigorous procedures, testing, data, and vast industry experience to determine appropriate shipping methods and set procedures to ensure compliance with them. The procedures ensure that Siemens' shipping methods are appropriate and that products are robust and not susceptible to material degradation from any temporary temperature fluctuations during shipment or otherwise.

The IVDs Siemens sells were developed over decades by Siemens or its predecessor companies acquired by Siemens Healthcare Diagnostics Inc. between 2006 and 2008. *See* Am. Compl. Ex. 5 at 1. At acquisition, each of these globally-operating predecessor companies had

[10] "Extremely Unlikely" means "less than 1 per 1,000,000 assays" and such events are "[n]ot expected to occur over designed product life." *See* Am. Compl. Ex. 10F at 68. "Negligible Health Risk" means that "[t]he combination of severity of the harm and the probability of occurrence of harm is sufficiently minimal to be compared to the acceptable risk of daily living." *Id.* Ex. 8 at 14, 10F at 68. For a "Low Health Risk," a justification of the risk is required, but is considered to be of sufficiently low impact that no formal risk benefit analysis is required. *Id*. Ex. 8 at 14.

its own robust procedures for testing products, which materially overlapped but were not identical. After 2008, Siemens finalized a unified internal procedure to "provide guidance on storage and shipping requirements to ensure the integrity of temperature controlled products during warehouse storage and distribution," ultimately called Diagnostics Quality System Procedure (DQSP)-00033. *See id.* By 2016, DQSP-00033 contained a list of more than 4,000 products with detailed description of storage and shipping conditions. *See id.* Ex. 4.

Since its inception and going back to when each product was launched, the shipping conditions specified in DQSP-00033 have been supported by studies of temperature ranges in the U.S. and Europe, as well as testing to account for circumstances where IVD products are likely to experience temperatures outside usual ranges (known as "excursions"). *See id.* Ex. 5 at 1–3.[11] Siemens uses thermal stress and stability testing to confirm that its IVD products will maintain integrity in extreme temperatures in the course of shipping and still continue to meet labeled performance specifications throughout their labeled shelf-lives. *See id.* Ex. 15 at 23. Notably, both the temperature ranges and the time periods used during these tests far *exceed* anything the products are likely to experience during shipping. For example, under current procedures, Siemens typically tests products that will be stored long-term in "refrigerated" conditions (approximately 36–46°F or 2–8ºC) for tolerance at three highly elevated temperatures compared to labeled storage temperature (Ambient Routine) conditions referred to as AR1, AR2, and AR3, and at one low temperature condition. *Id.* Ex. 6 at 14. Specifically:

- AR1 subjects a product to 30ºC (86°F) for 36 hours, followed by 35ºC (95°F) for 12 hours, followed by 45ºC (113°F) for 4 hours, i.e., a total of 52 hours at 30ºC (86°F) or more. *Id.* at 15.
- AR2 subjects a product to 25ºC (77°F) for 48 hours, followed by 30ºC (86°F) for

[11] Where specific data on shipping has been unavailable, Siemens has taken a conservative approach and used, as a proxy, the "the long-term storage temperature ranges … as responsible shipping conditions." *Id.* Ex. 5 at 3.

6 hours, i.e., a total of 54 hours at 25ºC (77°F) or more. *Id.*

- AR3 subjects a product to 15ºC (59°F) for 54 hours. *Id.*
- The low temperature condition mandates that Siemens "[f]reeze product at –20ºC [–4°F]. Thaw product to 2-8ºC [36–46°F] on Day 1, then refreeze product. Continue through 3 F/T [freeze/thaw] cycles of one day each." *Id*. at 14.

Samples are returned to storage after being subjected to these extreme temperatures and then tested at least through the period of the products' shelf lives to confirm they will continue to meet performance specifications throughout labeled shelf life. *Id.* at 14–15.

Based on this rigorous testing, Siemens ensures that its products are not susceptible to degradation from the customary conditions during shipping, and uses the data generated, as well as the experience and knowledge of its scientists and experts, to set shipping conditions. Siemens has also developed "rise/fall" codes to assist in determining how to handle reported temperature excursions outside of the standard ranges if they occur. *Id.* at 7 (§ 4.4.7). Under these procedures, if products are reported to have been exposed to environmental conditions that exceed certain limits, the products are quarantined until determination of final disposition. *Id.* at 5–8 (§§ 4.2.1(i),4.4.1–4, 4.5.1–4). Relator does not plead a single instance in which a product was found to have experienced a temperature excursion beyond tolerances but was used by a customer, let alone used to report a patient result and seek reimbursement.

iii. Siemens' typical IVD shipping requirements

Pursuant to the version of DQSP-00033 attached to the Amended Complaint, "refrigerated" products are "picked and packed at + 2º to + 8ºC or in a controlled ambient environment (+ 15ºC to + 25ºC) for a period not exceeding two hours" and "each warehouse must implement a one hour time limit as the standard process" leaving the second hour as "a buffer of time" for "exceptional cases." *Id.* at 4. To that end, box-type shippers "consist of an 'inner' polystyrene container with cold packs and packing inside of a cardboard box." Am.

Compl. Ex. 16 at 3, Ex.19 at 6. The cold packs (refrigerant) are preconditioned to a suitable temperature before they are added to the shippers. *See, e.g. id.* Ex. 12 at 1. Pallet-type shippers, also used for "refrigerated" products, "consist[] of large, sturdy, structural foam insulated panels with supporting outer cardboard side panels, tops, bottom and corner pieces all banded together on a pallet base," which are "outfitted with cold gel packs as required to maintain temperature." *Id.* Ex. 19 at 6. Frozen products are packaged in shippers that "consist of passive systems which utilize dry ice as the refrigerant and polystyrene as the insulating material." *Id.* Ex. 16 at 3. Temperature-sensitive products are generally shipped in the U.S. by "Next Day Air," *id.* Ex. 30 at 2, typically by FedEx, meaning they are usually delivered within 24 hours or less.

iv. Safety checks by clinical labs, hospitals, and other customers

Unlike pharmaceuticals, which may be self-administered by patients, Siemens' IVDs are only administered by sophisticated, expert clinical laboratories, hospitals, or physician practices. *See* Am. Compl. ¶¶ 77, 96, 110. These entities are subject to stringent regulations, accreditation requirements, and industry standards which mandate they perform multiple procedures to assess the integrity of IVDs *before* reporting patient results from them. For example, the federal Clinical Laboratory Improvement Amendments ("CLIA")[12] mandate quality standards for labs performing tests on human specimens for purposes of diagnosing, treating, or preventing disease or assessing health. 42 C.F.R. § 493.1250. All facilities that perform testing on "materials derived from the human body" for purposes of medical treatment must meet the CLIA requirements. 42 U.S.C. § 263a(a). Labs must be CLIA-compliant to receive government reimbursement for reported IVD test results. *See id.* § 1395x(s)(17).

Under CLIA, "the laboratory is responsible for having control procedures that monitor

[12] *See* Centers for Disease Control and Prevention, "CLIA Laws and Regulations," *available at* https://www.cdc.gov/clia/law-regulations.html.

the accuracy and precision of the complete analytic process." 42 C.F.R. § 493.1256(a). This includes "control procedures" to "[d]etect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance." *Id.* § 493.1256(c). When receiving a new lot of IVD reagent from Siemens or other IVD manufacturers, each clinical lab is responsible for verifying that the delivered lot is suitable for use before using it on any patient samples. *See id.* § 493.1256(e). They are likewise required to subsequently perform verification procedures using controls and calibrators at specified intervals pursuant to manufacturer instructions before generating patient results. *See id.* § 493.1256(a), (b), (f). A control material is an "external sample . . . run in parallel with patient samples to assess the analytical reliability of the total analytical test system." Am. Compl. ¶ 137 (citing FDA, Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices (Feb. 1, 1996) ("FDA Guidance")).[13] Calibrators are "reference sample(s)," as opposed to patient samples, that contain "samples of known values," allowing them to be used to check that the IVD is functioning properly before being used on patient samples. FDA Guidance at 1–2. In addition to these procedures, each clinician must use their own clinical judgment in interpreting test results, in light of the overall clinical picture for the patient. *See also* Am. Ass'n for Clinical Chemistry, "Troponin," (cited in Am. Compl. ¶ 135) ("Increased troponin levels are not to be used by themselves to diagnose or rule out a heart attack. A physical exam, clinical history, and ECG are also important.").

[13] *Available at* https://wayback.archive-it.org/7993/20170721174258/https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM094139; *see also* Am. Compl. Ex. 47 at 5-§2.1 (discussing the use of control samples having different concentrations of a target analyte to verify calibration, and acceptable ranges of analytical readings from such verification runs). This guidance was operative for the majority of the time covered by Amended Complaint and Relator relies on it for her allegations. *See also* FDA, *In Vitro Diagnostic Device Labeling Requirements*, *available* at https://www.fda.gov/medical-devices/device-labeling/in-vitro-diagnostic-device-labeling-requirements (calling for "[d]etails of calibration" and "[d]etails of necessary quality control procedures and materials") (last visited June 5, 2022).

Siemens' labeling aligns with all of these regulations and requires labs to run frequent quality control procedures in conjunction with its assays. The labeling includes directions to use Siemens or third-party calibrators and controls to assess that assays are functioning properly. For example, the labeling for Siemens' Centaur[14] TnI-Ultra assay (for cardiac troponin) provides detailed instructions on preparing calibrators for the IVD, including that the lab should calibrate not only every 28 days, but also "[w]hen changing lot numbers of primary reagent packs," "[w]hen replacing system components," and "[w]hen quality control results are repeatedly out of range." Ex. D (TnI-Ultra IFU) at 8, 9. It further instructs the lab to run controls on a daily basis. *Id.* And it yet further instructs customers specifically **not to report results** whenever "quality control results do not fall within the Expected Values or within the laboratory's established values." *Id.* at 10. If a delivered assay is not performing for *any* reason, no test results are permitted to be reported by a lab for any test that was run since the last successful QC and until the next successful one. *See* 42 C.F.R. § 493.1256(f) ("Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results."). Accordingly, a deficiency in a calibrator or control could potentially result in a failed quality check for an assay, but would not lead to an erroneous patient result. *See* Am. Compl. Ex. 47 at 4 (§ 1.2) (describing verification of system performance using calibrators and controls); *see also id.* Ex. 47 at 5 (§ 2.1), 6 (§ 3.3), 7 (§4.4.4).

In sum, a delivered test outside specifications will not result in either a reportable *patient result* or a claim for reimbursement. It likely would, however, result in a reportable *event*, including a complaint to Siemens and/or notice to the FDA, where appropriate. *See infra* at 15;

[14] The Centaur was one of several platforms sold by Siemens during the time referenced in the Amended Complaint. Platforms typically run a selection of IVDs.

see also Am. Compl. Ex. 47 at 7 (§4.4.4) ("[w]hen a specified quality control parameter is found to be out of limits …[t]he Contracting Officer shall be notified within 2 working days of any deficiencies in existing kits … [and the] FDA shall be notified according to its regulations"). Test failures will therefore not go unnoticed. That is why the ***lack*** of allegations of any such failures due to Siemens' shipping practices is not only noteworthy but also dispositive.

v. Siemens' post-shipping monitoring procedures

Siemens' shipping practices are also informed by "historical performance and/or routine product monitoring," Am. Compl. Ex. 6 § 4.1.2, including "**post**-production monitoring of performance in the field," *id.* Ex. 9 (FMEA for troponin) at 1; *see also id.* Exs. 10A-10E (FMEAs with same or similar statements). Review of customer complaints is an integral part of Siemens' procedures for monitoring its shipping practices and any impact on delivered IVDs. Given the sophistication of Siemens' highly-regulated customers and the quality control procedures they must continuously perform to maintain their licensing, damaged products will be identified. If customers do not detect any such problems, that is a very strong sign that Siemens' IVDs are functioning properly. *See, e.g.*, *id*. Ex. 10F at 63 ("There were no confirmed complaints during the six month review period (ending 11/23/2015). There were approximately 844,500 units sold representing 135,552,708 customer tests during the same period. Controls are effective in risk mitigation."); *id*. Ex. 35 at 9 ("Complaint review was conducted and it was found that our current shipping and transportation conditions had a negligible known adverse effect on the performance of our products."). As Relator concedes, when she raised concerns about Siemens' practices, the company promptly conducted a "[r]eview of complaint handling file" and did not find any systematic evidence of issues, which confirmed the "[r]isk to product performance and patient safety due to current shipping and handling practices is negligible to

low."[15] *Id.* Ex. 21 at 2; *see also id.* Ex. 35 at 2 ("No known product quality impact and the distribution practices have been in place for many years.").

Further, the FDA requires manufacturers and their lab customers to file Medical Device Reports ("MDRs") with the FDA promptly when devices malfunction or potentially contribute to a serious injury. *See* 21 C.F.R. §§ 803.30, 803.50.[16] Following an adverse event (for which labs must timely give notice), manufacturers report detailed information to the FDA about each event, including the nature of the potential problem and an explanation of any remedial actions taken. *See id.* §§ 803.30, 803.52. The Amended Complaint does not identify ***any*** MDRs involving an assay failure related to shipping.

D. Siemens' Shipping Container Studies

At various points, Siemens has retained consultants to develop information about the performance of its shipping containers (as opposed to the performance of its IVDs). Relator relies on studies by two such consultants, and claims they show that Siemens' IVDs could have been damaged during transit. But Relator's reliance on those studies is doubly flawed. First, she assumes that the FDA requires IVDs to be shipped at the same temperature that a customer is instructed to store them for long-term use (*e.g.*, if a product is labeled to be stored by a clinical laboratory at 2–8°C for a period of months or years for purposes of its shelf-life, Relator assumes that short-term shipments must always be maintained at that same temperature). As discussed above, that misstates the law. *See supra* at 6. Second, Relator assumes that *any* deviation from the long-term storage temperature for *any* amount of time is likely to result in a product being damaged. As discussed above, that is not true either. *See supra* at 17. Indeed, neither study says

[15] *See supra* at 9 n.10 for definitions of low and negligible risk.

[16] *See also* FDA, "Medical Device Reporting (MDR): How to Report Medical Device Problems," *available at* https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

anything about whether IVDs were shipped improperly or damaged.

In 2009, Siemens commissioned ISC Laboratories ("ISC") to conduct a multi-year study of "the anticipated temperature conditions that a package would encounter during transport." Am. Compl. Ex. 11 at 2. ISC placed probes within Siemens' shipment containers (*i.e.*, "shippers") and temperature data was recorded. Information gathered from this study was intended to be used "in developing a thermal packaging system for shipping temperature-sensitive products." *Id.* at 9. Critically, the study was **not** designed to, and did **not**, evaluate whether the integrity or performance of any Siemens' IVD products was negatively impacted due to any temperature excursions while in transit. *See id.* at 1–3.

The data showed that in many instances Siemens' shippers maintained temperatures within 2–8ºC / 36–46°F (*e.g.*, refrigerated long-term storage for Siemens' IVDs) over extended periods of time. For example, in winter, the product probes maintained that range for over 20 hours in Siemens' smaller and medium shippers. *Id.* Ex. 12 at 1–3, 10–12. In summer, product probes registered temperatures under 8ºC for 24 to 36 hours. *See id.* Ex. 13 at 1. Thus, to the extent long-term storage temperatures are relevant to short-term shipping, ISC confirmed they were generally maintained during transit. While temperatures exceeded that range in some instances, the study did not evaluate and provided no information on product integrity or performance from the shipping container experiencing temperatures outside 2–8ºC.

In 2015, Siemens engaged a firm called BioConvergence to conduct other studies of Siemens' shippers, including a simulated (*i.e.*, lab-based) test and a field test. *Id.* Ex. 15 at 10. In the field testing, the shippers were equipped with internal and external temperature probes and placed in U.S. and international shipping lanes, subjecting them to "extreme cold temperatures" during February and March and "extreme hot temperatures" during the summer. *Id.* Ex. 16 at 3.

While the inner probes were placed within the individual shipping container or pallet, BioConvergence's protocol did not call for any probe to be placed inside or directly in contact with an actual IVD product in the container—the study measured only box temperatures. *Id.* at 4. Further, for purposes of its analysis, BioConvergence used all data gathered over a 72-hour period "regardless of delivery time," even if the shipper was delivered before then. *Id.* at 6. It then rated a shipper as "Fail" if it experienced any internal temperature outside of 2–8°C *at any point* during the 72-hour period (while making no measurement of the temperature of the enclosed IVD). *Id.* at 5–7.[17] The study nonetheless confirmed that the shippers often maintained temperatures within 2–8°C for 36 hours. *Id.* Ex. 30 at 3. As with the ISC study, to the extent long-term storage temperatures are relevant, the BioConvergence study suggested they were generally maintained in the shipping containers during normal U.S. shipping times.

Siemens had good reason to be cautious about relying on any of BioConvergence's conclusions. As BioConvergence conceded in its report, in conducting the study it deviated from its agreed-on protocol in multiple respects. For example, with regard to the field "cold" test, Siemens instructed BioConvergence to simulate normal circumstances by shipping the products on a Tuesday or Wednesday, but it failed to do so, shipping them on a Thursday with the result that many shipments were held over the weekend, resulting in misrepresentative data. *Id.* Ex. 16 at 12. This is inconsistent with Siemens' normal practice of next-day air shipment. *See supra* at 12. Likewise, BioConvergence used expired materials for the test, which "could not be shipped using the standard process" and were not tendered to the carrier on the same day, as required.

[17] Further, in making its Pass/Fail determination on simulated test data, BioConvergence took "into account temperature readings for all internal probes" and "[i]f one probe within one test sample recorded results outside of the acceptance criteria [2-8 ºC or < -20 ºC] for the protocol the shipper is deemed to have failed the test." Am. Compl. Ex. 17 at 4. The protocol did not make any attempt to conform to the actual temperature ranges experienced by Siemens' products.

Am. Compl. Ex. 16 at 12. BioConvergence admitted this discrepancy may have negatively impacted the gel icepacks used for cooling, thereby impacting the temperatures recorded in the study. *Id*. As a commentator noted in reviewing the findings of the report, "[t]hese statements [about the deviations noted above, and others] negate the entire protocol. As a result[,] the protocol(s) should be assessed as Failures and should not be utilized for any conclusions . . . ." *Id.* Ex. 16 at 13. The report to Siemens expressly stated "[a]ny interpretation of the data as an indication of performance would not be appropriate." *Id.* Ex. 15 at 32 (emphasis added). In sum, the BioConvergence study was not designed to measure IVD performance in any way, and BioConvergence's flawed approach severely limited its use for any purpose.

E. Claims for Reimbursement for Siemens' IVDs

"Siemens does not submit the claims itself" for reimbursement of IVD products it sells to customers. Am. Compl. ¶ 84. Instead, Siemens' customers—*e.g.*, clinical laboratories and hospitals—submit claims for reimbursement to health insurers (including government programs) based on their use of IVDs purchased from Siemens. *See id.* Relator offers no factual allegations related to *any* third-party submission of claims for reimbursement on Siemens' IVDs—nothing, for example, regarding customers that submitted claims; the IVDs for which they sought reimbursement; the amounts or dates of their submissions; what, if any, certifications they made; and, critically, whether any particular submission was false or sought reimbursement for a product that was defective. Relator appends a handful of spreadsheets to the Amended Complaint, but they merely identify certain IVDs that the federal and state governments purchased from Siemens. There is no information about how or when they were used and what conditions or transit times related to shipping were associated with their delivery. *See id.* Exs. 3,

3A–3F.[18] Although Relator attaches a single contract between Siemens and the Veterans' Administration and a handful of purchase orders and RFPs from or with government agencies (some of which are unsigned or not even filled out), none identify specific tests that were actually used, performed, or reported. *See id.* Exs. 2, 47–49.

Relator alleges that "Siemens also sold those compromised IVD products directly to the government in violation of both express and implied contract payment terms," Am. Compl. ¶ 172, but Relator critically fails to identify any such "express or implied" payment terms and fails to allege with any particularity how any such terms were violated by Siemens' actual shipping practices. In fact, the Amended Complaint does not allege *any* representations by Siemens regarding temperature control during shipping, or any certifications made by (or caused by) Siemens related to government payment. Further, it does not identify a single instance in which the government paid (either directly or via reimbursement) for a Siemens' IVD that failed to meet its performance specifications as a result of Siemens' shipping practices.

F. Relator's Very Brief Tenure with Siemens

Between May and December 2015, Relator was employed by BioConvergence and consulted with Siemens. Am. Compl. ¶¶ 10, 115 & Ex. 19. BioConvergence terminated Relator's employment for reasons that are not clear from the Amended Complaint and that were not shared with Siemens. Am. Compl. Ex. 31 at 21. Subsequently, Siemens briefly retained Relator as an individual consultant from February 17, 2016 through April 29, 2016. As a consultant, Relator was supposed to work on projects related to shipping of IVDs. *See id.* ¶ 10 & Ex. 31 at 21.

Unbeknownst to Siemens, at the time she was hired as a consultant, Relator had already

[18] Relator refers to certain "terms and conditions" for the government purchases identified in Exhibits 3B-3F, without citation. Am. Compl. ¶¶ 91–95. None of the terms and conditions relates to shipping temperatures.

filed at least one sealed *qui tam* action against other medical device manufacturers.[19] Relator misused her position as a consultant to try to concoct a claim against Siemens as well. Less than two weeks after starting as an individual consultant, Relator leveled accusations about Siemens' processes in an email to senior management, which she herself conceded was "alarmist," particularly in light of her very short tenure and limited knowledge of the company. *See id.* Ex. 31 at 1. Shortly after her engagement with Siemens, Relator began to surreptitiously record conversations with Siemens employees.[20] Relator also quickly set out to steal confidential and proprietary documents from Siemens, including materials that had nothing to do with her job as a consultant. *Id.* ¶¶ 6, 112, 145, 151, 158–61, 169 & Exs. 3, 4-47. And Relator, a temporary consultant in a very limited role, contacted at least one of Siemens' suppliers regarding alternative packaging for Siemens' products without involving any Siemens employees in that process. *Id.* ¶¶ 166–68 & Exs. 36, 37, & 39.

Relator asserts that the documents she misappropriated and the recordings she covertly engineered contain "admissions" demonstrating that Siemens was knowingly shipping products under circumstances that would pose a risk to public health. *See id.* ¶ 179. For example, Relator alleges that a Siemens employee expressed concerns about the BioConvergence report, noting that it "rais[ed] too many questions rather than deliver[ed] answers." *Id.* ¶ 150. But as discussed above, in light of the flawed execution of the BioConvergence study, this comment was entirely warranted, as the report did not reflect the shipping methods Siemens used or measure IVD temperatures. *See supra* at 18–19. Relator also purports to take issue with Siemens' examination of customer complaints in the course of evaluating its shipping procedures. Am.

[19] *See U.S. ex rel. Wood v. Avalign Techs., Inc.*, No. 14 Civ. 4958 (ER), 2020 WL 2555115, at *1 (S.D.N.Y. May 20, 2020) (noting complaint was filed on July 2, 2014).

[20] Relator has declined to provide Siemens with copies of the recordings, despite a request she do so.

Compl. ¶ 156. Yet Siemens' complaint handling was entirely appropriate and consistent with FDA procedures. Siemens' customers are sophisticated entities with their own obligation to ensure assays run properly and patient results are accurate. *See supra* at 15. Nor does Relator allege that the complaint review indicated any systemic issues with Siemens' practices.

Relator points to a statement purportedly made by a Siemens employee that certain individuals were "freaking panicked" about concerns she raised about potential shipping issues, including the troponin assays. Am. Compl. ¶ 158. But the fact that Siemens took the concerns raised by Relator seriously does not mean its processes were flawed; rather, it means that the employees were both vigilant and responsive to potential issues. And although Relator accuses a Siemens employee of being resistant to opening Corrective and Preventive Actions ("CAPAs") with respect to shipping issues, she does not dispute that Siemens opened multiple CAPAs, and that haphazardly opening CAPAs—as Relator apparently wanted—would, itself, violate company procedures and FDA rules. *Id.* ¶ 159 & Ex. 31 at 16, Ex. 34.

G. Relator's Serial Complaints and the Government's Investigations

Relator filed her initial complaint relating to Siemens' shipping practices on August 16, 2016, in the Southern District of New York (the "SDNY Action"), soon after her engagement with Siemens expired. *See* Ex. E. Over the ensuing three and a half years, the U.S. Attorney's Office for the Southern District of New York (the "SDNY USAO"), with the assistance of FDA personnel, conducted a lengthy and extensive investigation into Relator's allegations. After completing its investigation with full cooperation from Siemens, the SDNY USAO filed a notice on January 31, 2020, stating that the United States, as well as the District of Columbia and all 28 States named as co-plaintiffs, declined to intervene in the action. *See* Ex. F. Relator did not serve Siemens with her original complaint. Instead, Relator waited several months, and then on April 28, 2020, Relator filed an amended complaint, which she served on Siemens. *See* Ex. G.

That complaint is ***substantially identical to the current one***.

On July 2, 2020, Siemens submitted a letter to the court in the SDNY Action asking the court to unseal the docket and permit Siemens to file a motion to dismiss Relator's amended complaint. Ex. H. That same day, before the court ruled on Siemens' letter, Relator informed Siemens that she was dismissing her claims without prejudice, which she proceeded to do, before the court had any opportunity to review Siemens' motion. Ex. I. The court thereafter dismissed the action. Ex. J.

For the next nine months—despite what Relator alleges to be very serious risks of Siemens' shipping practices—Relator did nothing. Then on April 12, 2021, she filed a new Complaint in this Court that was substantially identical to the one she had unsuccessfully pursued in SDNY. *Compare* Ex. G *with* ECF No. 1. Once again, the Government—this time, the U.S. Attorney's Office for the Eastern District of New York ("EDNY USAO")—expended resources to investigate, and yet again, the United States, the District of Columbia, and the 30 states named as co-plaintiffs declined to intervene. ECF No. 17-2. This Court then ordered Relator to serve the Complaint on Siemens on December 14, 2021, along with the Government's declination. Relator did not comply with that order. Instead, on March 29, 2022, Relator filed the Amended Complaint (ECF No. 8), which she did not serve on Siemens until April 11, 2022. ECF Nos. 10–11. The Amended Complaint is yet again materially the same as Relator's original EDNY Complaint and the Amended Complaint she had voluntarily dismissed in the SDNY Action. *Compare* ECF No. 1 *with* ECF No. 8, and ECF No. 8 *with* Ex. G.

Relator does not allege the FDA or any other federal or state agency has taken *any* enforcement action against Siemens as a result of her allegations or based on any information the Government learned during the course of its exhaustive investigations. Instead, Relator concedes

that during the investigations and through today, the government continues to enter into contracts with Siemens for the purchase of millions of IVD tests and to reimburse claims for test results from Siemens' assays—notwithstanding Relator's wild allegations that Siemens' shipping practices pose ongoing "extremely serious public health risks" and have caused the government billions of dollars in damages. Am. Compl. ¶¶ 162, 173; *see also id.* ¶¶ 101, 112, 153. Relator makes no attempt to reconcile the government's actions—or lack thereof—with her claims.

ARGUMENT

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must contain "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Gamm v. Sanderson Farms, Inc*., 944 F.3d 455, 462 (2d Cir. 2019) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted)). While the Court must accept as true "well-pleaded factual allegations in the complaint" and draw "all reasonable inferences in favor of the nonmoving party," *id.*, it is "not required to credit conclusory allegations or legal conclusions couched as factual . . . allegations," *Nielsen v. Rabin*, 746 F.3d 58, 62 (2d Cir. 2014) (internal quotation marks omitted). On a Rule 12(b)(6) motion, the court may consider the complaint itself, "any written instrument attached to it as an exhibit, materials incorporated in it by reference, and documents that, although not incorporated by reference, are integral to the complaint." *Sasson Plastic Surgery, LLC v. UnitedHealthcare of N.Y., Inc.*, No. 17-CV-1674 (SJF), 2021 WL 1224883, at *1 (E.D.N.Y. Mar. 31, 2021) (internal quotation marks omitted); *see also Jackson v. Nassau Cty.*, 552 F. Supp. 3d 350, 365 (E.D.N.Y. 2021). A "court need not accept as true the allegations in a complaint when they are contradicted by documentary evidence from the exhibits attached to that complaint." *Best v. Schneider*, No. 12-CV-6142 (NGG), 2015 WL 5567062, at *10 (E.D.N.Y. Sept. 21, 2015).

To plead a claim under the FCA, Relator must allege that Siemens (i) made a claim (or

caused a claim to be made) (ii) to the United States Government (iii) that is false or fraudulent (iv) where Siemens knew of that falsity and (v) where the claim sought payment from the United States. *See U.S. ex rel. Qazi v. Bushwick United Hous. Dev. Fund Corp.*, 977 F. Supp. 2d 235, 238–39 (E.D.N.Y. 2013). And Relator is further required to allege that Siemens' alleged failure to comply with the relevant FDA regulations was material to the government in deciding whether to pay or reimburse for any of the IVDs at issue. *Universal Health Servs. v. U.S. ex rel. Escobar*, 579 U.S. 176, 194–95 (2016). And Relator's allegations related to Siemens' allegedly fraudulent scheme and any claims paid by the government must all be pleaded with particularity under Rule 9(b). *See U.S. ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 26 (2d Cir. 2016).

The Amended Complaint fails to meet these requirements on multiple grounds. *First*, Relator has failed to plead facts that state a facially plausible claim, as required by Rule 12(b)(6). For Relator's claims to be true, Siemens would have had to ship **billions** of IVDs under improper conditions leading to flawed patient results and resulting false claims, without any detection by its sophisticated, CLIA-regulated customers, medical professionals, the FDA, or the two U.S. Attorneys' Offices that have conducted intensive investigations. The utter implausibility of such a far-reaching scheme is more than sufficient reason to dismiss the Amended Complaint.

Second, Relator has failed to meet Rule 9(b)'s requirement that she plead her claims with particularity. Despite her claims of a long-running fraudulent scheme, Relator cannot identify a single IVD that was damaged as a result of shipping, or a single instance where such an IVD reported an incorrect test result. Nor can she identify a single payment made by the Government related to such a claim that was false due to an incorrect result or false certification.

Third, Relator has failed to plead falsity. Relator premises her case on a theory of "legal falsity," asserting that Siemens made or caused others to falsely certify its compliance with its

regulatory obligations based on her erroneous contention that the FDA requires device manufacturers to ship their products under the same conditions as their long-term storage. But because FDA regulations simply do ***not*** contain that requirement, no such false certifications can be alleged. And even if Relator could allege a regulatory violation (which she cannot), that would be insufficient to sustain an FCA claim.

Fourth, Relator has failed to plead materiality. Even if Relator had alleged a viable regulatory violation (she has not), Relator has not adequately pleaded any violation likely to influence the government's decision to pay for results from Siemens' products. To the contrary, Relator's pleading and the record in this matter demonstrate that any purported violation must be seen as ***im***material as a matter of law, especially in light of multiple Government investigations and the government's continued purchase and use of Siemens' IVDs, as well as its continued reimbursement for test results from such IVDs by hospital and laboratory systems.

Relator's failure to plead any viable FCA claim means her conspiracy claims and other state claims should likewise be dismissed. Moreover, given her repeated failed attempts to plead a viable complaint and her gamesmanship with regard to serial refiling of the same claims in different forums, the Amended Complaint should be dismissed, this time *with prejudice*.

I. RELATOR'S CLAIMS ARE IMPLAUSIBLE ON THEIR FACE

To survive this motion to dismiss, Relator's complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell. Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads *factual content* that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (emphasis added). A pleading that offers only "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Relator's claims are inherently implausible and should be dismissed.

Relator alleges that "in order to save costs" Siemens chose to ship its IVDs under conditions that it knew were noncompliant and likely to cause damage. Am. Compl. ¶ 5. Relator never specifies how much Siemens allegedly saved, but speculates it was enough to motivate Siemens to ship billions of tests in such a way to "destroy[] the assurances of testing accuracy and reliability so essential to any IVD product." *Id.* ¶ 7. This, in turn, purportedly led to labs using degraded assays, and the government spending "many millions of taxpayer dollars" on the IVDs and the "procedures using these devices." *Id.* ¶ 8. According to Relator, this conduct went on for years (and still continues), and involved senior Siemens management, including from transportation, quality management, logistics, and compliance. *Id.* ¶¶ 134, 144.

Relator fails to plead any facts whatsoever to support these outlandish accusations. If Siemens had engaged in the widespread misconduct alleged in the Amended Complaint, there would unquestionably be evidence of defective products and shipments, as well as voluminous customer complaints, myriad erroneous testing results and misdiagnoses, and ample data showing systemic problems. Presumably there would also be a pattern of increased customer and/or clinician complaints or product failures from months and/or locations with extreme temperatures. No such facts are alleged here, because none exist. If any did exist, they undoubtedly would have been uncovered during the many years of investigation by the SDNY and EDNY U.S. Attorney's Offices and thereafter made their way into the pleadings.

Further, Relator does not (and cannot) plead that the FDA has ever taken any enforcement action against Siemens related to its shipping of IVD products (or ever suggested that Siemens should change its methods) or that any government entity stopped paying for any Siemens' IVDs or sought to recoup past payments. It is inconceivable that this would be the case if Relator's speculative and conclusory allegations had any validity. Nor does Relator plead facts suggesting

Siemens' shipping practices are inconsistent with industry standards, or that other IVD manufacturers ship products in the manner Relator claims is *required*. It is not plausible that Relator (lacking any relevant IVD performance expertise) is the lone authority on how to ship IVD products, while Siemens, other manufacturers, laboratories, industry standard-setting bodies, FDA, and the Government are all getting it wrong and have done so for decades. This is inherently implausible and reason alone to dismiss the Complaint.

II. RELATOR FAILED TO PLEAD WITH THE REQUISITE PARTICULARITY

A complaint alleging a violation of the FCA must comply with the pleading requirements for a fraud claim set forth in Rule 9(b). *See U.S. ex rel. Chorches for Bankruptcy Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017); *Ladas,* 824 F.3d at 26. A plaintiff alleging fraud under the FCA must plead specific facts showing that a defendant submitted or caused the submission of a false or fraudulent claim to the government. *Chorches*, 865 F.3d at 83. This includes not only the details of the underlying fraudulent scheme, but also particularized allegations regarding ***actual*** false claims submitted to the government. *See U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04-CV-0704 (ERK), 2009 WL 1456582, at *5 (E.D.N.Y. May 22, 2009) (relator must plead specific facts regarding "[u]nderlying schemes and other wrongful activities that result in the submission of fraudulent claims" as well as "actual false claims submitted to the government" (internal quotation marks omitted)). Here, Relator's claims fail on both counts—she has not pleaded with particularity any facts showing that any of Siemens' IVDs were ever damaged due to shipping conditions and then used to report results on patient samples (the "underlying scheme[]" or "other wrongful activity"), and she has not pleaded with particularity any facts showing that any of Siemens' customers submitted "actual false claims" to the government.

A. The Complaint Fails to Plead Particular Facts of a False or Fraudulent Scheme

The Second Circuit has established that a *qui tam* action must be dismissed where the complaint contains only "hypotheses" but not factual allegations sufficient to satisfy Rule 9(b). *See Ladas*, 824 F.3d at 26–27 ("Although the [complaint] contained hypotheses as to how problems with the integrity of the power supply case's surface *could* affect the devices ordered by the government," it lacked any "allegation that the seemingly aesthetic deficiencies in the power-supply casings *had in fact* affected the form, fit, or function of any device." (emphases added)). In *U.S. ex rel. Gelbman v. City of New York*, the Second Circuit affirmed dismissal of a relator's complaint for failure to satisfy Rule 9(b) when the complaint failed to "put[] forth particularized allegations" of a fraudulent scheme. 790 F. App'x 244, 248 (2d Cir. 2019). While the relator in *Gelbman* "assume[d]" that NYSDOH submitted false claims because the claims had previously been flagged as ineligible, the relator only "allege[d] in a conclusory fashion that his superiors at NYSDOH 'conspired' with an unknown number of unidentified 'HRA representatives' to 'manipulate and rig'" the Medicaid reimbursements, which was not enough to survive a motion to dismiss. *Id.*; *see also U.S. ex rel. Corp. Compliance Assocs. v. New York Soc'y for the Relief of the Ruptured & Crippled*, 2014 WL 3905742, at *16 (S.D.N.Y. Aug. 7, 2014) (dismissing FCA claims where plaintiff failed to allege "a single example of an identified physician providing a service to a patient" that was falsely coded or any specific instances of inappropriate referrals).

The same is true here. At most, Relator alleges that certain data from the ISC or BioConvergence studies *could* suggest that Siemens' shippers *might* experience temperature excursions, which *could* have an impact on the performance of products contained therein. *See supra* at 16. But despite having access to Siemens' internal data and years to mine the public record (not to mention the benefit of two Government investigations into the allegations and

Siemens' practices), Relator does not identify *a single shipment—**out of more than 100,000 products shipped every month***, Am. Compl. ¶ 110,—that *actually* experienced a temperature excursion sufficient to affect product performance. Nor does she identify any instance in which a customer (highly-sophisticated, licensed labs) complained about products arriving damaged or failing the required quality control procedures. *See supra* at 11. Nor does she identify a single instance in which a Siemens IVD led to an erroneous patient result due to conditions of shipment. While Relator singles out the troponin assay as "representative," Am. Compl. ¶¶ 134–46, it is representative of nothing relevant here. She does not allege that any troponin assay—or any other assay—ever experienced a temperature excursion during shipment that affected its performance or returned an erroneous patient result. *Id.* Indeed, Relator implicitly concedes that she does not have any specific facts to support her claim that shipping issues actually extend to all Siemens IVDs (or any particular IVDs), alleging only on information and belief that "Siemens uses the same few shipper designs and procedures for all products regardless of temperature requirements." *Id.* ¶ 111. This fails to satisfy her burden under Rule 9(b).

B. The Complaint Fails to Plead Any Particular False Claims

The submission of a false claim to the government is the "sine qua non of FCA liability." *U.S. ex rel. Gelman v. Donovan*, No. 12-CV-5142 (RJD), 2017 WL 4280543, at *6 (E.D.N.Y. Sept. 25, 2017). Even if Relator had properly pleaded the existence of a fraudulent scheme—which she has not—her complaint still must be dismissed because it fails to allege with particularity specific facts regarding the labs or hospitals that allegedly submitted false claims for Siemens' IVDs, the allegedly adulterated or misbranded IVDs for which a third-party submitted a claim, or even a date on which a false claim was submitted.

The court dismissed an FCA complaint in *U.S. ex rel. Siegel v. Roche Diagnostics, Corp.*, 988 F. Supp. 2d 341 (E.D.N.Y. 2013), for this exact reason. There, the relator alleged that

Roche's fluid testing machine produced false positive results when testing for the presence of phencyclidine and that each instance in which a medical provider billed the government for reimbursement constituted a false claim. *Id.* at 342–43. The court dismissed the *qui tam* action, holding that "there is nothing in the complaint alleging with particularity that a claim was submitted to the Government for reimbursement," and that "[i]t is insufficient to allege that the submission of a false claims is merely conceivable or even likely." *Id.* at 346 (internal quotation marks omitted); *see also Johnson v. Univ. of Rochester Med. Ctr.*, 686 F. Supp. 2d 259, 265 (W.D.N.Y. 2010) ("[A]llegations of violations of federal regulations or laws are insufficient if a plaintiff cannot identify with particularity *any actual false claims* submitted by defendant to the government." (internal quotation marks omitted)). Here, Relator's wholly conclusory and entirely speculative allegation that "Siemens caused others to submit false claims to Federal Health Care Programs," Am. Compl. ¶ 171; *see also id.* ¶¶ 15, 82, 176, 179(e), is equally insufficient.

Instead of pleading specific facts, Relator hypothesizes that third parties *may* have submitted false claims because Siemens is a large manufacturer of IVDs. Relator alleges that Siemens serves approximately 13% of the global IVD market, 45% of which is in the U.S, and therefore it is "inevitable" that claims for products made by "an IVD manufacturing colossus like Siemens" will reach the government. *Id.* ¶¶ 78, 82. But the fact that claims for IVDs manufactured by Siemens "inevitably" reached the government says nothing about whether any such claims related to IVDs were *false*. This type of "market-share"-based allegation is insufficient to meet the standards of Rule 9(b). *See U.S. ex rel. Osmose, Inc. v. Chem. Specialties, Inc.*, 994 F. Supp. 2d 353, 366 (W.D.N.Y. 2014) (holding that relator's "market-share theory of causation is patently insufficient under . . . Rule 9(b)"). Moreover, as outlined above,

federal law and Siemens' labeling specifically require receiving customers to perform quality control and calibration procedures to assess that the shipped IVDs function properly. *See supra* at 14. Relator's allegations and a "market share" theory provide no basis to infer that any hospital or lab ever submitted a claim to the government based on inaccurate results that would render them false, particularly where end-user quality control and calibration procedures are specifically designed to prevent non-complying IVD from being used on actual patient samples.

In fact, Relator's allegations about market share affirmatively *undermine* her claims. As noted, if Siemens' procedures were broadly deficient (as Relator implausibly alleges), given how many tests Siemens ships in the U.S, its market share, and the multi-year governmental investigations into Relator's allegations, it is simply inconceivable that there would be no identifiable evidence of such deficiencies reflected in patient results or customer complaints. Yet the Amended Complaint concedes that Siemens' robust internal review of complaints confirmed there was no evidence of Siemens' practices causing product defects during the customary conditions of distribution. *See supra* at 15. This is fatal to Relator's claims.

Effectively conceding that she cannot plead particular facts, Relator asks the Court to draw the supposedly "common sense inference" that false claims were submitted to the government. *See* Am. Compl. ¶ 82 (alleging that the Court may simply assume that fraudulent claims arising from the use of Siemens' IVDs were reimbursed by federal health care programs). In support of this proposition, Relator points to two cases to justify her failure to meet the standard of Rule (9)(b): *Chorches* and *U.S. ex rel. Omni Healthcare Inv. v. McKesson Corp.*, No. 12-cv-6440, 2019 WL 438357 (E.D.N.Y. Feb. 4, 2019). *See* Am. Compl. ¶ 80. In *Chorches*, the Second Circuit held that a plaintiff could only be relieved of the obligation to identify specific false claims where "the facts are peculiarly within the opposing party's knowledge," and the

complaint "adduce[s] specific facts supporting a strong inference of fraud." 865 F.3d at 81-82 (internal citations and quotations omitted).[21] But Relator's allegations are nowhere close to meeting this standard. The most specific allegations in the Amended Complaint are quoted conversations of Siemens employees that Relator recorded, and the dates of those recording. *See supra* at 21. But none of those conversations relates to details about claims submitted to the government. Moreover, the exception allowed in *Chorches* is permissible only when the facts are in the *defendant's* particular knowledge, which is not the case here, where evidence would have been available (if it existed) from labs, hospitals, the FDA, and public records. *See Siegel*, 988 F. Supp. 2d at 346 (refusing to relax Rule 9(b) pleading standard where "there is no reason to believe that [the defendant] had any knowledge of false claims that were submitted by third-party medical providers"). Relator's reliance on *McKesson* fares no better. There, the court permitted the plaintiff to plead the submission of false claims on information and belief only because the plaintiff alleged that it itself had submitted such claims, and the distributor defendants conceded that the claims submitted by the plaintiff had been pleaded with particularity. 2019 WL 438357, at *10. A case in which a plaintiff pleads the submission of some claims on personal knowledge and other claims on information and belief is a far cry from this case, where *all* of Relator's allegations concerning the submission of false claims are based on pure speculation.

III. RELATOR CANNOT SHOW THAT ANY CLAIMS WERE FALSE

To plead a claim under the FCA, a relator must show that claims for payment submitted

[21] In *Chorches*, the relator was prohibited from entering the building where the defendant performed its billing, making it "virtually impossible" for the relator to have personal knowledge about particular claims. 863 F.3d at 82. The Second Circuit held the relator met his burden under Rule 9(b) because the "allegations detail[ed] specific and plausible facts from which we may easily infer . . . that AMR systemically falsified records to support false claims," including the "names [of] supervisory personnel" who instructed him to falsify records, as well as details regarding "many specific [ambulance] runs—providing information such as the date, patient name, and original reason for the transport" for which he was told to improperly alter information. *Id*. at 83–84. These facts bear no resemblance at all to the speculative and non-specific allegations here.

to the government were false or fraudulent. *Chorches*, 865 F.3d at 83. Under the FCA, claims are either "factually" false or "legally" false. Factually false claims "involve[] an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *U.S. ex rel. Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001), *overruled in part on other grounds by Escobar*, 579 U.S. 176. Legally false claims are "predicated upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term." *Id.* at 696.

Relator does not allege Siemens failed to provide (or customers did not use) assays that were submitted to the government for payment, and thus must be proceeding on a theory of legal falsity. Legally false claims can be express or implied. "[U]nder a theory of express certification, a plaintiff must allege that the defendant submitted 'a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.'" *United States v. N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, 293-94 (E.D.N.Y. 2016) (quoting *Mikes*, 274 F.3d at 698). Under an implied certification theory, a plaintiff must allege "first, [that] the claim does not merely request payment, but also makes *specific* representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 579 U.S. at 190 (emphasis added).

Relator's complaint is silent as to whether Siemens allegedly made an express or implied certification, contending only that Siemens distributed IVDs in "violation of federal legal requirements designed to assure the devices' safety and efficacy." Am. Compl. ¶ 1; *see also id.* ¶¶ 59–76.[22] But Relator fails to identify any certification that Siemens either made or caused to

[22] Relator also claims Siemens violated a contractual commitment to customers to ship reagents in "insulated thermal containers against thermal (Heat/Cold) damage which would affect reagent performance." Am. Compl.

be made that was false. Relator points only to the FDA-mandated QSR requirements, alleging that Siemens somehow "failed to comply with any of [them]." *Id.* ¶¶ 105–06. But these regulations do not require Siemens to ship its assays at their long-term storage temperatures as Relator asserts. *See supra* at 6. The FDA instead requires that manufacturers "ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution." 21 C.F.R. § 820.130. As the Amended Complaint and attached exhibits demonstrate, Siemens has adopted and follows such procedures. Likewise, the FDA does not require manufacturers to describe shipping conditions on the device labels. *See supra* at 5. The long-term storage requirements included on the IVD labels, *see* Am. Compl. ¶¶ 53–57, make no representations—let alone *misrepresentations*—about the device's shipping conditions.

Even if Relator could show that Siemens violated an applicable regulation (which she cannot), that would be insufficient to state a claim without evidence of a false statement or a fraudulent course of conduct. *See Koshy v. Regeneron Pharm., Inc.*, 2019 WL 6895563, at *6 (S.D.N.Y. Dec. 18, 2019) (dismissing claim where plaintiff had not pleaded any evidence of fraud, since "[a]t most, plaintiff was concerned [defendant] would violate FDA regulations because of its allegedly deficient quality control mechanisms"); *see also U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702–03 (4th Cir. 2014). Courts have repeatedly held that the FCA is not intended to be used as a vehicle to enforce garden-variety regulatory violations. *See Escobar*, 579 U.S. at 194; *Rostholder*, 745 F.3d at 702–03. "When an agency has broad powers to enforce its own regulations, as the FDA does in this case, allowing FCA liability based on regulatory non-compliance could short-circuit the very remedial process the Government has

¶ 74. But this requirement is entirely consistent with Siemens' actual shipping practices. *See supra* at 12.

established to address non-compliance with those regulations." *Rostholder*, 745 F.3d at 702 (internal quotation marks omitted); *see also U.S. ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 620 (2d Cir. 2016) (warning that "even in its broadest application, [the FCA] was never intended to be used as a back-door regulatory regime to restrict practices that the relevant federal and state agencies have chosen not to prohibit through their regulatory authority" (internal quotation marks omitted)). This is particularly true for violations of cGMPs—regulations that afford manufacturers broad discretion to implement procedures best suited to their specific products. *See Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 278–79 (E.D.N.Y. 2009) (cGMPs "leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective"). In fact, courts have made clear that the FDA does not require perfection to comply with QSR. *See Sekisui Am. Corp. v. Hart*, 15 F. Supp. 3d 359, 378 (S.D.N.Y. 2014). The FDA recognizes that errors will periodically occur and thus "expects manufacturers to investigate and correct non-conformities through their CAPA systems." *Id.*; *see also Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 162 (S.D.N.Y. 2011) (regulations do not require manufacturers to remedy every issue and some problems "are never resolved, but the failure to resolve a problem does not necessarily mean that the manufacturer violates federal regulations"). Opening appropriate CAPAs in accordance with its procedures to address potential process issues is precisely what Siemens did here consistent with that regulatory construct. *See supra* at 22.

Rostholder is illustrative of the demarcation federal courts have drawn separating regulatory violations from viable FCA claims. There, the relator alleged that the manufacturer was repackaging penicillin in violation of the cGMPs. 745 F.3d at 698. The Fourth Circuit held that even if the drug was adulterated, Medicare did not require compliance with cGMPs and

therefore payment requests could not constitute a "false" claim under the FCA on the "sole basis" that the drug was being processed in violation of the regulations. *Id.* at 702 ("Were we to accept relator's theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct."). In *Rostholder*, it was undisputed that the drug at issue was adulterated, but the court still found that insufficient to serve as a basis for a claim under the FCA. There is even less support here, where the Relator's conclusory allegation that Siemens violated FDA regulations in its shipping practices is premised on her erroneous positioning of what the FDA actually requires. *See U.S. ex rel. Colucci v. Beth Israel Med. Ctr.*, 785 F. Supp. 2d 303, 314–15 (S.D.N.Y. 2011) (rejecting a relator's attempt to rely on general principles underlying a law where she could not identify a "specific provision" that supported her reading of it and the regulations belied her assumptions).

Finally, the Amended Complaint notes that Siemens took steps to avoid any temperature excursions for international shipments to China. Am. Compl. ¶ 169. But as Relator concedes, the Chinese government sets different requirements for shipping IVDs into China, due to the significant additional time involved in shipping products there from the U.S., customs processing upon entry, and subsequent distribution. *Id.* The Chinese government can, of course, set its own requirements, but this has nothing to do with whether the FDA has set similar requirements—it has not. Relator's contentions ignore that the duration and complex logistics of shipment to distant international locations present very different challenges and concerns compared with far more expeditious shipments within the U.S. from Siemens' centrally-located facility in Indiana. *See id.* ¶ 11. Here, too, the Amended Complaint fails to make out a claim under the FCA.

IV. RELATOR'S ALLEGATIONS FAIL TO PLEAD MATERIALITY

The Amended Complaint also fails to plead materiality, another required element under the FCA. As the Supreme Court has held, to survive a motion to dismiss, a plaintiff must plead that compliance with a regulation was material to the government's payment decision. *Escobar,* 579 U.S. at 194–95. This standard is both "demanding" and "rigorous." *Id.* at 192, 194.

As discussed above, Siemens did not (and is not required to) ship assays at labeled long-term storage temperatures, and it made no certifications that it did. And to the extent Relator is attempting to ground her claim on a purported discrepancy between Siemens' own internal processes and it practices, this too cannot provide a basis for an FCA claim for the numerous reasons explained above. Moreover, under either theory, the Amended Complaint fails to allege that any representation was made by Siemens or was material to the government.

Two U.S. Attorney's Offices have undertaken an in-depth investigation into Relator's allegations—one spanning multiple years and utilizing considerable federal resources—and both Offices elected ***not*** to intervene. *See supra* at 2. What's more, the Amended Complaint does not allege that the FDA has used any of the extensive enforcement powers, such as inspections, warning letters, or market interventions, to take issue with Siemens' shipping practices. To the contrary, Relator asserts that the government continues to process reimbursements for tests performed using Siemens assays, and that as recently as 2019 the government entered into new contracts to buy Siemens' IVDs. Am. Compl. ¶¶ 86, 88; Ex. 47. (It did the same in 2020-2022.) Yet, as Relator concedes, Siemens has not materially changed its shipping practices. *Id*. ¶ 162.

The continuing payment and lack of any action by the government following Relator's multiple Complaints demonstrates that any issues raised by Relator are not a material consideration for its continuing purchases and reimbursement. "[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that

is very strong evidence that those requirements are not material." *Escobar,* 579 U.S. at 195; *see also U.S. ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (no materiality where FDA "continued its approval" of a drug and, in six years, the government took no action against the defendant and declined to intervene); *U.S. ex rel. D'Agostino v. EV3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016) ("FDA's failure actually to withdraw its approval of [the device] in the face of [relator's] allegations precludes" a finding of materiality).[23] The fact that the government would do *nothing* while Siemens was shipping billions of tests under allegedly unsafe conditions, while paying billions of taxpayer dollars to reimburse labs and hospitals using those tests fatally undermines any claim of materiality, and provides yet another basis for dismissal. *See U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35 (1st Cir. 2017) (no materiality "when an agency armed with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position").[24]

V. RELATOR'S CONSPIRACY CLAIM FAILS

Relator's conspiracy claims, Am. Compl. at ¶¶ 188–91, fails for at least two reasons. First, Relator has failed to plead an underlying FCA violation, for all the stated reasons above. Simply put: "[w]ithout an underlying violation, there can be no liability for conspiracy under the FCA." *U.S. ex rel. Petratos v. Genentech, Inc.*, 141 F. Supp. 3d 311, 317 n.3 (D.N.J. 2015), *aff'd*, 855 F.3d 481 (3d Cir. 2017); *see also U.S. ex rel. Kasowitz Benson Torres LLP v. BASF*

[23] *See also U.S. ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 541–42 (10th Cir. 2020) (no materiality where government conducted an investigation, but continued to pay claims); *United States v. Sanford-Brown Ltd.*, 840 F.3d 445, 447–48 (7th Cir. 2016) (agency's decision to continue payments after investigation was evidence of immateriality); *U.S. ex rel. Kolchinsky v. Moody's Corp.*, No. 12-cv-1399, (WHP), 2018 WL 1322183, at *3-4 (S.D.N.Y. Mar. 13, 2018) (no materiality where government continued to make payments and entered into new contracts with defendant); *United States v. Cath. Health Sys. of Long Island Inc.*, No. 12-CV-4425 (MKB), 2017 WL 1239589, at *23 (E.D.N.Y. Mar. 31, 2017) (government's decision to continue to reimburse, even though it knew of alleged fraudulent non-compliance with reimbursement rates, is "strong evidence" the government did not consider compliance material to payment).

[24] For the reasons stated, the Amended Complaint should be dismissed with prejudice in its entirety. In addition, though not pertinent to this motion, any claim before April 21, 2015, is time-barred. *See* 31 U.S.C. § 3731(b)(1)-(2).

Corp., 929 F.3d 721, 728–29 (D.C. Cir. 2019). Second, "the intracorporate conspiracy doctrine bars FCA conspiracy claims where all the alleged conspirators are either employees or wholly-owned subsidiaries of the same corporation." *U.S. ex rel. Chilcott v. KBR, Inc.*, No. 9-cv-4018, 2013 WL 5781660, at *12 (C.D. Ill. Oct. 25, 2013); *see also Hartline v. Gallo*, 546 F.3d 95, 99 n.3 (2d Cir. 2008) ("[U]nder the intracorporate conspiracy doctrine, officers, agents and employees of a single corporate entity are legally incapable of conspiring together."). Here, Siemens Healthcare Diagnostics Inc. is a wholly-owned subsidiary of Siemens Medical Solutions USA, Inc., and Siemens Healthcare Diagnostics Products GmbH is an affiliate of Siemens Healthcare Diagnostics Inc, Am. Compl. ¶¶ 11–13, and each of them is indirectly wholly-owned by Siemens Healthineers AG. The only allegations in the Amended Complaint relate to these entities (or their agents and employees).

VI. RELATOR'S CLAIMS SHOULD BE DISMISSED WITH PREJUDICE

The Amended Complaint should be dismissed with prejudice. This is Relator's fourth pleading asserting the same claims, and Relator has already exercised her right to amend under Rule 15(a). *See U.S. ex rel. D'Agostino v. EV3, Inc.*, 802 F.3d 188, 193 (1st Cir. 2015); *see also Com. Lubricants, LLC v. Saftey-Kleen Systems, Inc.*, No. 14-cv-7483, 2019 WL 2492752, at *3 (E.D.N.Y. June 14, 2019) (Brodie, J.) ("motions to amend 'should generally be denied in instances of futility, undue delay, bad faith or dilatory motive, [and] repeated failures to cure deficiencies by amendments previously allowed … .'") (citations omitted)). After six years, two rigorous Government investigations, and untold opportunities to marshal facts, it is clear Relator has no case. Any effort to prolong this matter further would be futile, unwarranted, abusive to Siemens, and a further waste of government and judicial resources.

CONCLUSION

For the foregoing reasons, Relator's Amended Complaint should be dismissed with prejudice.

Dated: June 17, 2022
New York, New York

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